

qrulepubliccomments

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Subject: Public Comment - 42 CFR 70 and 71
Importance: High
Attachments: HCPHES 42 CFR 70 & 71 Comment 1-9-06.doc

Good afternoon -

Attached you will find comment from Harris County Public Health and Environmental Services regarding the proposed changes to 42 CFR 70 and 71.

Please let me know if you have any questions.

Elizabeth

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HCPHES Comment Regarding the Proposed Revision to 42 CFR 70 and 71: Control of Communicable Diseases

Harris County Public Health and Environmental Services (HCPHES) has concerns regarding both the feasibility of the proposed changes to 42 CFR 70 and 71 in practice as well as there being little mention of collaboration with local/state health authorities and other relevant entities at the state and local levels. Regarding the feasibility of these changes, the key concern is the current lack of infrastructure (particularly personnel) to carry out measures such as passenger screening, provisional quarantine, quarantine, medical monitoring and sanitary measures, as well as the lack of enforcement capacity. HCPHES recommends that this section be revised to include language requiring the Centers for Disease Control and Prevention (CDC) to ensure appropriate staff and other infrastructure to carry out the duties outlined in 42 CFR 70 and 71, including the enforcement of these provisions. These staff may be federal employees (e.g. CDC employees) or agreements may be developed with local/state/other federal agencies to ensure appropriate capacity for specified duties.

Regarding the involvement of local jurisdictions, it is crucial that local and state health authorities be informed and involved in order to develop and ensure rapid implementation of appropriate control measures in the community. HCPHES proposes that these regulations be revised to include directives to CDC requiring close collaboration with existing local, state and federal entities/programs (e.g. local health agencies or local Metropolitan Medical Response System planning groups) in the planning and implementation of activities outlined in the 42 CFR 70 and 71.

Following is HCPHES comment on proposed changes within key sections of 42 CFR 70 and 71:

42 CFR 70 – Interstate Quarantine

42 CFR 70.1 – Scope and Definitions

This section outlines the scope of the provisions and adds or modifies a number of relevant definitions, such as “airline,” “business day,” “carrier,” “detention,” “emergency contact information,” “flight information,” “infectious agent,” “interstate traffic,” “medical monitoring,” “public health emergency,” “qualifying stage” of a disease, “quarantine,” and “sanitary measure.” These definitions have been added or updated to be consistent with modern travel, commerce and

public health practice. **HCPHES concurs with these changes. Most definitions appear to be reasonable and logical.**

Of note, the definition of “ill person” has been expanded to include a person who has any of the following: a temperature above 100.4° F for more than 48 hours or that is accompanied by certain other symptoms; diarrhea; certain symptoms such as severe bleeding, jaundice or severe persistent cough that is accompanied by certain other symptoms; or “displays other symptoms or factors that are suggestive of communicable disease...” This definition is significant because, as according to analysis found in the Federal Register, “... it determines the scope of the reporting requirement” found later in Part 70. This refers to the reporting of on-board occurrences of illnesses to health authorities by non-medical persons (e.g. flight crews). Discussion of this will appear in the comment regarding 42 CFR 70.2.

HCPHES requests that language be clarified to indicate whether the provisions within 42 CFR 70 apply only to flights conducting interstate travel or to all flights (interstate or intrastate) operated by any airline carrier that offers interstate flights. That is, clarification to indicate whether the provisions also apply to intrastate travel conducted by airlines that engage in interstate travel.

42 CFR 70.2 – Report of Death or Illness on Board Flights

This section mandates that airlines operating flights in interstate traffic must report any deaths or illnesses that occur on board to CDC as soon a death or illness is reported to the aircraft commander and (when possible) at least one hour before the flight’s arrival. Further, the section states that CDC may order airlines operating a flight in interstate traffic [presumably one from which a report of death or illness has just come] to disseminate to passengers and crew recommended public health notices, measures and information.

Current regulations require that persons in charge of carriers engaged in interstate traffic in which a suspected case of communicable disease develops must notify the local health authorities at the next port of call, station or stop “as soon as practicable” and take such measures as the local health authority requires. Thus there are two key changes to the regulations. First, the proposed regulation requires that airlines report occurrences of death or illness in a more immediate fashion. **HCPHES believes that the need for this change is great, as a major challenge to implementing the appropriate public health interventions (investigations, control measures, etc.) following an occurrence of suspected communicable diseases on board flights is the reality that airlines do not currently report such incidences to the local authorities in a expeditious manner, if at all. The proposed regulation should address this challenge to some degree, though enforcement may be difficult.**

Second, the revised language replaces the requirement that carriers must report to local health authorities with the requirement that they report directly to CDC. There is merit to the analysis’ reasoning that “by providing a single point of contact..., the burden on carriers to identify and maintain points of contact with local health authorities is significantly reduced,” which may lead to increased compliance with reporting requirements. However, as the authorities appointed to administer state and local laws relating to public health within the appointees’ jurisdictions, local

health authorities such as the Executive Director of HCPHES have a vested interest in being made aware of and being involved in matters relating to reports of death or illness on board interstate flights arriving in their jurisdictions. **HCPHES proposes that the proposed Section 70.2 be revised to require CDC to notify the local health authorities within one hour of receipt of reports from carriers regarding occurrences of death or illness on board interstate flights. The appropriate local health authorities should include those from the jurisdictions where a flight originated and arrives. Further, HCPHES proposes that the proposed Section 70.2 be revised to require CDC to consult with the local health authorities regarding subsequent measures taken to prevent the introduction, transmission or spread of communicable diseases. Such measures may include those described in subsequent sections, such as provisional quarantine, quarantine, medical monitoring, sanitary measures, etc.**

The success of implementing these two key changes to Section 70.2 is dependent upon the capacity of the personnel aboard the carrier to recognize an “ill person” and be aware of the proper protocol subsequent to this recognition. Because personnel aboard carriers do not, in most cases, have a medical background, and there are no mechanisms for on board medical examinations, the recognition of an “ill person” is dependent upon the descriptive definition described in the discussion about Section 70.2 above. As the analysis states, the definition is “broad by design” and ensures that “all situations for which the [CDC] must take action in order to prevent the introduction and spread of communicable disease are reported.” Therefore, while there are certain to be instances when reporting may not have been necessary, “a narrower definition would likely exclude situations of public health significance, thus circumventing the very purpose for which the reporting requirement is designed.” **HCPHES concurs with the need to rely on non-medical personnel (e.g. flight crews) to use their judgment to apply a broad, descriptive definition of “ill person” in order to recognize persons potentially ill with a communicable disease.**

42 CFR 70.4 – Passenger Information

This section mandates airlines operating flights in interstate travel to solicit from each passenger and crewmember certain information, including full name, emergency contact information, email address, home address, passport number (for foreign nationals only), names of traveling companions, flight information, returning flight (if relevant) and current phone number (can be mobile, home, pager or work). Airlines must maintain this information in an electronic database for 60 days from the end of the flight, and submit it electronically to CDC within 12 hours of a request. Airlines must provide passengers with a written explanation of the purpose for soliciting this information. Passengers who decline to provide this information will not be barred from traveling.

Personal correspondence with CDC Quarantine Officers stationed at Bush Intercontinental Airport (IAH) informed HCPHES that in general, airlines do not currently solicit such information on passengers. The information that is collected in order to process flight reservations is not maintained beyond a very brief few-hour time subsequent to the flight, if such information is maintained at all. Further, information about where passengers were seated during flights are maintained in a hard copy paper format only, and are stored in a manner that makes efficient and timely review extremely difficult. **Therefore, HCPHES concurs with the requirement that airlines solicit and maintain electronically the information needed to implement basic public health disease control protocols, including efficiently identifying, locating and evaluating**

persons who may have been exposed to a communicable disease during travel with the goal of protecting the persons exposed and preventing further disease transmission. **HCPHES concurs with the requirement that airlines submit electronically to CDC the electronic database of passenger information within 12 hours of a request.** However, HCPHES proposes that the proposed section 70.4 be revised to require CDC to electronically submit this information to the local health authorities within one hour of receipt from the airline. The appropriate local health authorities should include those from the jurisdictions where a flight originated and arrives.

Regarding the utility of each proposed data element, HCPHES believes that the need for “traveling companions” may not be necessary, as those persons will have completed an information form as well. In addition, collecting returning flight information from passengers may not be the appropriate data element to determine a person’s destination, as many people may not have return flight information at their disposal. Rather, “how to be reached at destination” (e.g. hotel name, etc.) might be a better element to capture this. In addition, airlines could automate the data entry of the return flight information if the traveler will be returning on their airline.

In addition, HCPHES suggests that airlines consider adopting automated methods for collecting passenger information in order to decrease the burden on the passenger and the time required to collect information. HCPHES suggests that airlines consider collecting key parts of the information at the following two points – as part of airline frequent-flyer membership sign-up/renewal and/or at the time of flight booking. At flight check-in the airline could present a copy of this information to the passenger to determine if any updates are required.

42 CFR 70.6 – Travel Permits

This section prohibits persons who know they are in the qualifying stage of a quarantinable disease from traveling from one U.S. state or possession into another unless they have a written permit from the CDC. Further, this section prohibits carriers operating interstate traffic from transporting any person whom the operator knows to be in the qualifying stage of a quarantinable disease unless the person presents a written travel permit issued by the CDC. This section allows the CDC to apply these provisions to intrastate travel – that is, travel entirely within a state or possession – “if the [CDC] determines that such person’s travel or the carrier’s operation will have an effect on interstate commerce.” However, this must be upon the request of a state or local health authority. **HCPHES questions the efficacy of this requirement due to the difficulty in enforcement. HCPHES requests clarification regarding the mechanism that will be used to inform persons in the qualifying stages of quarantinable diseases as well as operators of carriers regarding travel permit requirements, as well as the intended means for enforcement.**

42 CFR 70.9 – Vaccination Clinics

This section updates an existing section in 42 CFR 70 authorizing CDC to establish vaccination clinics to administer vaccines “and/or other prophylaxis” and to add a provision stating that the CDC may charge persons who are not enrolled in Medicare Part B with an administration fee. The proposed updates require that such vaccination clinics comply with guidance from CDC regarding recordkeeping and safe vaccine administration, handling, monitoring and storage. Specifically, the requirements include the collection and maintenance of such information as the age, gender and prior vaccination history of the vaccine recipient, the vaccine lot number, the date of vaccination, reason for vaccination, concurrent vaccinations, information relevant to the Vaccine Adverse Events Reporting System and verification that the vaccination conferred immunity (if applicable). All such requirements may be waived or modified by CDC in the event of a public health emergency.

HCPHES requests clarification on the applicability of this section. First, HCPHES seeks clarification on the scope of these clinics – do these provisions apply only to clinics established at an airport or other port for situations relevant to interstate travel? HCPHES also seeks clarification on whether the proposed requirements apply to vaccination clinics established by entities other than CDC, such as public health departments, private entities and community-based organizations. In addition, HCPHES seeks clarification on the term “or otherwise” in the following language – “The Director may establish vaccination clinics, through contract or otherwise....”

42 CFR 70.10 – Establishment of Institutions, Hospitals and Stations

This section authorizes CDC to enter into “voluntary agreements with public or private institutions for the purpose of establishing places for care and treatment,” which could include such places as quarantine stations or treatment centers for persons under quarantine. **HCPHES proposes that the language be revised to require that this occur following consultation with and concurrence of local health authorities, as such authorities may have previously-established agreements for similar purposes.**

42 CFR 70.11 – Sanitary Measures

This section authorizes CDC, when there is reasonable belief that a carrier affecting interstate commerce (or any animal, article or thing on board) may be infected or contaminated with a communicable disease and “in consultation with other federal agencies as appropriate” to inspect the carrier and order it to carry out certain sanitary measures necessary. **HCPHES proposes that the language be revised to allow for consultation with “such other federal, state and local agencies as appropriate” in order to ensure that the appropriate expertise is applied to each individual situation.**

42 CFR 70.12 – Detention of Carriers Affecting Interstate Commerce

This section authorizes CDC, “in consultation with such other federal agencies as appropriate” to detain carriers affecting interstate commerce until any recommended sanitary measures have been carried out. **HCPHES proposes that the language be revised to allow for consultation with “such other federal, state and local agencies as appropriate” in order to ensure that the appropriate expertise is applied to each individual situation.**

42 CFR 70.13 – Screenings to detect ill persons

This section authorizes CDC to conduct screenings of persons or groups of persons at airports or other locations to detect the presence of ill persons. The language specifies that screening may include such methods as “visual inspection, electronic temperature monitors and other methods determined appropriate by CDC.” **HCPHES concurs with intent of this section and supports the need to specify the possible screening methods.**

42 CFR 70.14 – Provisional Quarantine

This section authorizes CDC to provisionally quarantine passengers or groups of passengers at airports or other ports of entry who CDC reasonably believes to be in the qualifying stage of a quarantinable disease. According to the analysis, the intent of the provisional quarantine order is to detain persons who withhold consent for voluntary screenings in order to determine if they are in the qualifying stage of a quarantinable disease. This authority derives from the Public Health Service Act, which authorizes the “apprehension, detention or conditional release of persons to prevent the introduction, transmission and spread of certain communicable diseases from foreign countries into the United States and from one State or possession into another.”

Because the intent of provisional quarantine is to determine if persons are in a qualifying stage of a quarantinable disease, generally the provisional quarantine period would only be as long as the time needed to determine whether the person is a carrier of the disease. However, the proposed language specifies that a provisional quarantine may last up to three business days. According to the analysis, this period of time was derived based on the usual time frame needed to collect specimens for testing, ship specimens to an appropriate laboratory, perform culturing and microorganism identification and integrate test results with findings from other investigations. The analysis states that there is legal precedence for the establishment of such a time period and the time period does allow for the requirements of due process. If there is a need to continue to detain persons beyond the period allowed by a provisional quarantine, CDC may serve quarantine orders.

The section states that persons subject to provisional quarantine may be offered medical treatment, prophylaxis or vaccination as appropriate. Persons may refuse such measures but may remain subject to provisional quarantine.

HCPHES supports the establishment of mechanisms for provisional quarantine as it relates to interstate travel. HCPHES supports the mechanism proposed in Section 70.15 for carrying out provisional quarantine orders.

However, HCPHES proposes that the maximum period of time for which a provisional quarantine may be applied be revised to 72 hours from the point of quarantine rather than three business days. If occurring over a weekend and Monday holiday (e.g. Labor Day, etc.), the period of provisional quarantine could potentially be up to six days (144 hours), twice the length of the usual time frame that the analysis states is needed to determine whether a person is a carrier of a disease. HCPHES believes that due to the current reality that public health agencies and personnel are considered to be “first responders” with

regard to emergency support functions, CDC should be able to ensure 24/7 availability following a provisional quarantine situation. This may be a more prudent approach in light of the fact that a person's movement has been restricted.

The section states that a person may refuse medical treatment, prophylaxis, etc., but if they do so they remain subject to provisional quarantine. The section also states that in the event that CDC determines that it is necessary to provisionally quarantine a person (or group of persons) beyond three business days then CDC shall serve the person with a written quarantine order. Presumably CDC will make the determination that a person requires quarantine based on medical and epidemiological data gathered during the provisional quarantine period. However, if a person refuses medical diagnostics or treatment it is unclear how the determination for the necessity of a quarantine order will be made. **HCPHES requests clarification regarding the transition from provisional quarantine to quarantine in the instance that a person refuses medical diagnostics and treatment during the provisional quarantine period.**

42 CFR 70.16 – Quarantine

This section authorizes CDC to quarantine passengers or groups of passengers at airports or other ports of entry who CDC reasonably believes to be in the qualifying stage of a quarantinable disease. This belief may be based on, but not limited to clinical manifestations, epidemiologic information, diagnostic or medical tests, physical examination or other evidence of exposure or infection. As with provisional quarantine, the intent of the quarantine order is to detain persons who withhold consent for or do not comply with voluntary quarantine. The section states that CDC may offer medical treatment, prophylaxis or vaccination as necessary in accordance with the quarantine order. Further, CDC may quarantine persons who refuse examination, medical treatment, prophylaxis or vaccination or persons for whom these measures may be contra-indicated or unavailable.

The length of time for which CDC may quarantine persons may not exceed the period of disease incubation and communicability, as determined by CDC. That is, a person with a potential exposure to a quarantinable disease may be under quarantine for the disease's typical incubation period. If that person does not become ill from the disease, the person may be released after the incubation period expires. However, if a person does become ill, the person will be isolated for the period of communicability. The language allows for an opportunity to request an administrative hearing to review the quarantine order, as well as judicial review. **HCPHES supports the enhancement of mechanisms for federal quarantine as it relates to interstate travel, and concurs with the provisions described in this section.**

42 CFR 70.19 – Medical Monitoring

This section authorizes CDC to order medical examinations or monitoring of passengers or groups of passengers at airports or other ports of entry who CDC reasonably believes to be in the qualifying stage of a quarantinable disease. Persons subject to medical examination/monitoring must provide CDC with information that may be needed to develop and implement appropriate epidemiological investigations and disease control measures, such as information regarding familial and social contacts, travel itinerary, medical history, place of work and vaccination status. Persons may refuse medical examination and monitoring, but those who do remain subject to provisional quarantine or

quarantine. **HCPHES supports the need for medical examinations or monitoring in order to develop and implement the appropriate disease control measures, and concurs with the provisions described in this section.**

42 CFR 70.24 – Requests by State (Including Political Subdivisions Thereof), Possessions or Tribal Health Authorities

This section states that a health authority of a state, locality, possession or Indian tribe may request that CDC “take public health measures in accordance with this part” (that is, Part 70) as well as “whatever further public health measures that [CDC], in consultation with the health authority, deems necessary to prevent the introduction, transmission, or spread of communicable diseases.” Because this statement could limit a health authority’s control following the health authority’s request to CDC, it is important that a health authority be well-informed about the implications of such a request. **HCPHES proposes that provisions be added stating that this section does not preclude CDC from providing consultative assistance upon the request of health authorities in their efforts to develop and implement public health measures to prevent the introduction, transmission or spread of communicable disease. Further, HCPHES proposes that the language be revised to state that the health authority may request that CDC take “whatever further public health measures that the Director, in consultation with and concurrence of the health authority” deems necessary.**

42 CFR 70.25 – Measures in the Event of Inadequate Local Control

This section is similar to an existing section in 42 CFR 70, which authorizes CDC to take measures to prevent the spread of communicable diseases between states or between states and possessions if CDC determines that measures taken by states, localities or possessions are insufficient. **HCPHES requests clarification on the manner in which this determination will be made by CDC. In addition, HCPHES proposes that the language be revised to state that rather than authorizing CDC to “take measures to prevent the spread of communicable disease” whenever CDC determines that the measures at the local/state level are “insufficient,” CDC will “offer to assist, supplement and/or strengthen measures taken by states, localities or possessions to prevent the spread of communicable disease.”**

42 CFR 70.29 – Penalties

This section states that persons in violation of this part are subject to a maximum fine of \$250,000 and/or a year in jail (or as otherwise provided by law), and violations by organizations are subject to a maximum fine of \$500,000 per event (or as otherwise provided by law). **HCPHES requests clarification on the burden of proof that would be necessary to charge persons, as well as organizations, with a violation of this part.**

42 CFR 71 – Foreign and Possessions Quarantine

Note – in general, many of the proposed changes to 42 CFR 71 mirror those in 42 CFR 70. Therefore, some HCPHES comments regarding 42 CFR 71 may reference those made above regarding 42 CFR 70.

42 CFR 71.1 – Definitions and General Provisions

This section is similar to 42 CFR 70.1, with some differences in the terms that are defined. See HCPHES comments above.

Of note, unlike provisions in 42 CFR 70 that requires CDC to make findings that a person is “in a qualifying stage of a quarantinable disease and moving or about to move from a state to another state or who is a probable source of infection to persons so moving or about to move” in order to implement many of the provisions of 42 CFR 70, there are no such provisions or requirements in 42 CFR 71 for persons entering the U.S. from a foreign country or U.S. possession.

42 CFR 71.6 – Report of Death or Illness on Board Flights

The provisions outlined in this section, applicable to airlines operating international flights destined for a U.S. port, are similar to those found in 42 CFR 70.2. See HCPHES comment above.

42 CFR 71.8 – Report of Death or Illness on Board Ships

This section establishes requirements for reporting on board illness and death applicable to shiplines operating ships on an international voyage destined for a U.S. port (but exempting ships operating between certain ports between Canada and the U.S.). The provisions require that a shipline must report to the CDC quarantine station nearest the port of arrival any deaths or ill persons among passengers or crew as soon as they are made known to the ship’s commander, and where possible, at least 24 hours before arrival. Shiplines must report any deaths or ill persons that occurred on board during the 15 day period prior to the expected arrival at a U.S. port (or the period since departure from a U.S. port, if shorter). **Similar to comments made in response to 42 CFR 70.2, HCPHES proposes that the proposed Section 71.8 be revised to require CDC quarantine stations to notify the local health authorities within one hour of receipt of reports from carriers regarding occurrences of death or ill persons on board. The appropriate local health authorities should include those from the jurisdictions where travel originated (if within the U.S.) and arrives. Further, HCPHES proposes that the proposed Section 70.2 be revised to require CDC to consult with the local health authorities regarding subsequent measures taken to prevent the introduction, transmission or spread of communicable diseases.**

In addition, shiplines must report to the quarantine station or other authorized representative 24 hours before a ship’s arrival the number of cases of diarrhea, febrile respiratory disease, febrile rash illness or febrile neurologic illness in passengers and crew recorded in the ship’s medical log during the current cruise, even if the number is zero.

42 CFR 71.10 – Passenger Information

This section is similar to 42 CFR 70.4, except that it is also applicable to ships on an international voyage (excluding ships operating between certain ports between Canada and the U.S.). See HCPHES comments above.

42 CFR 71.13 – Sanitary Measures

This section is similar to 42 CFR 70.11. See HCPHES comments above.

42 CFR 71.14 – Detention of Carriers

This section is similar to 42 CFR 70.12. See HCPHES comments above.

42 CFR 71.16 – Screenings to Detect Ill Persons

This section is similar to 42 CFR 70.13. See HCPHES comments above.

42 CFR 71.17 – Provisional Quarantine of Arriving Persons

This section is similar to 42 CFR 70.14. See HCPHES comments above.

42 CFR 71.19 – Quarantine

This section is similar to 42 CFR 70.16. See HCPHES comments above.

42 CFR 71.22 – Medical Examination and Monitoring

This section is similar to 42 CFR 70.19. See HCPHES comments above.

42 CFR 71.29 – Special Provisions Relating to Airports: Office, Examination and Quarantine Facilities

This section requires that airports that receive international traffic must provide, without cost to the government, suitable office, examination, quarantine and other exclusive space for carrying out functions related to disease control measures under 42 CFR 71. Personal correspondence with CDC Quarantine Officers stationed at IAH informed HCPHES that there is currently not adequate examination or quarantine space at IAH. In particular, there is not adequate space for the quarantine of groups of persons. Further, CDC staff reported to HCPHES that authorities at IAH have not responded positively for requests from CDC Quarantine Officers to identify designated space for the quarantine of groups of persons. **Therefore, HCPHES supports the provisions outlined in this section requiring that airports must provide adequate office, examination and quarantine space at or near the airport facility for carrying out disease control functions. HCPHES recommends that this section be applicable to airports receiving international traffic as well as those receiving interstate traffic.**

42 CFR 71.31 – Penalties

This section is similar to 42 CFR 70.29. See HCPHES comments above.